



Technical Specifications

Eclipse



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Eclipse Specifications

1.1 Eclipse Software Module Overview

1.1.1 EP15/EP25/VEMP Modules

Test types/functionality:	EP15	EP25	VEMP
Stimulus level	0 – 100 dB nHL	0 – 100 dB nHL	0 – 100 dB nHL
Click stimulus	x	x	x
Broadband CE-Chirp® & CE-Chirp® LS stimuli	Optional	x	
Narrow Band CE-Chirp® & CE-Chirp® LS stimuli (0.5, 1, 2, 4 kHz)	Optional	x	
Tone Burst stimuli (0.25 – 4kHz)	x	x	x
Recording window	15 and 30 ms	Up to 980 ms	150 ms
ABR	x	x	
Rate Study	x	x	x
ECochG	Optional	x	Optional
MLR		x	
ALR		x	
MMN/P300		x	
eABR	x	x	
cVEMP / oVEMP	Optional	Optional	x
EMG controlled stimulus/recording			x
EMG scaling (rectification)			x
Patient EMG monitor/tone			x
Research module *	N/A	Optional	Optional

* Research Module is a module license that enables the export of averaged curves, the data logging of individual sweeps and the import of WAV file stimuli. The exported data can be analyzed further in software such as MS Excel and Matlab programs. The research module includes the sound stimuli Da, Ga and Ba for ABR and MMN testing. Please refer to the Research module brochure or relevant chapter in the Instructions for Use manual for further information.

1.1.2 TEOAE25 Module

Test types/functionality:	TEOAE Module
Stimulus level	50 – 90 dB SPL
Linear click stimulus	x
Non-linear click stimulus	x
Stimulus bandwidth	400 – 4000 Hz
Test time	25 – 32000 sweeps
FFT display	x
1 kHz pass/refer bands, 1/3, 1/6, 1/12 octave band display	x
SNR value display	x
OAE level display	x
Automated screening (pass/refer) algorithm (protocol)	x
User definable pass/refer algorithm (protocol)	x
Password protection of test parameters	x

1.1.3 DPOAE20 Module

Test types/functionality:	DPOAE Module
Stimulus level	30 - 75 dB SPL (70 dB for freq. above 6kHz)
Stimulus range	500 – 8000 Hz
Test time	Min 2 sec – unlimited
DP-Gram	x
DP Input/Output	x
Normative data display option	x
Checkmark indication for SNR detection	x
User definable protocols	x
Manual test time override	x

1.1.4 ABRIS Module

Test types/functionality:	ABRIS Module
Stimulus type	Click
Stimulus rate	93 Hz
Stimulus intensity	30, 35, 40dB nHL
Test time	120 seconds (default)
Test montage	mastoid or nape
Test method	monaural
User customizable protocols	x
Password protection of test parameters	x

1.1.5 ASSR Module

Functionality:	ASSR Module
Stimulus level	0 – 100 dB nHL
Narrow Band CE-Chirp® stimuli (0.5, 1, 2, 4 kHz)	x
Recording time	Up to 15 min per curve
Stimulus rate	40 or 90 Hz
Transducer options	Headphone, Inserts, Bone
nHL to eHL correction factors (Child/Adult)	x
Residual noise calculator	x
User customizable protocols	x
Noah 4 and higher compatibility	x

1.2 Included and Optional Parts

Included parts:

EP15/EP25/VEMP	DPOAE20/TEOAE25	ABRIS	ASSR
Eclipse EPA Preamplifier EPA4 cable collector USB cable Power cable LBK15 Insert phone including eartips Neonatal Insert Ear tips 4.0 mm, 3.5 mm ETB Standard Electrode Cables with Buttons Pinch Clip Electrode Cables NuPrep gel 4oz/114g tube (SPG15) Gauze Swabs PEG15 Pregel foam snap electrodes (25 pcs) Alcohol Pads Ten20 Electrode Paste 8 oz/228 jar EP15/25/VEMP software OtoAccess™ software Instructions for Use Manual on CD Additional Information Manual on CD EP25: ECochG Starter Kit including cable, gel and 2 electrodes	DPOAE20 Eclipse OAE Probe complete Power cable USB cable DPOAE20 software BET25 Ear Tip Assortment Box Cleaning tool Probe tips OtoAccess™ Software Instructions for Use Additional Information Manual TEOAE25 Eclipse OAE Probe complete Power Cable Country specific USB connection cable TEOAE25 software BET25 Assortment Box with ear tips for OAE Cleaning tool Probe tip OtoAccess™ Software Instructions for Use Manual on CD Additional Information Manual on CD	Eclipse EPA Preamplifier EPA4 cable collector USB cable Power cable Insert phone including eartips Neonatal Insert Ear tips 4.0 mm, 3.5 mm ETB Standard Electrode Cables with Buttons Pinch Clip Electrode Cables NuPrep gel 4oz/ 114 g tube (SPG15) Gauze Swabs PEG15 Pregel foam snap electrodes (25 pcs) Alcohol Pads Ten20 Electrode Paste 8oz/228 g jar ABRIS software OtoAccess™ software Instructions for Use Manual on CD Additional Information Manual on CD	Eclipse EPA Preamplifier EPA4 cable collector USB cable Power cable Insert phone including eartips Neonatal Insert Ear tips 4.0 mm, 3.5 mm ETB Standard Electrode Cables with Buttons Pinch Clip Electrode Cables NuPrep gel 4oz/114g tube (SPG15) Gauze Swabs PEG15 Pregel foam snap electrodes (25 pcs) Alcohol Pads Ten20 Electrode Paste 8oz/228 g jar ASSR software OtoAccess™ software Instructions for Use Manual on CD Additional Information Manual on CD

Optional parts:

Refer to the current Sanibel Disposables & Accessories brochure (www.interacoustics.com) or contact your local distributor.

1.3 Technical Specifications

Technical Specifications - Eclipse Hardware

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	Safety:	IEC 60601-1, Class I, Type BF and IEC 60601-1-1, Class I, Type BF
	EMC:	IEC 60601-1-2
	Test signal:	IEC 60645-1/ANSI S3.6 IEC 60645-3 IEC 60645-7, Type 1
Power Supply:	Input Volts:	100 –240V, 50/60Hz.
	Consumption:	26 W (0.3A Max).
	Safety:	IEC 60601-1 class I, UL2601
Operating environment:	Operating Temperature:	15 – 35 °C (59 - 95°F)
	Rel. Humidity:	30 – 90%
Transport & Storage:	Storage Temperature:	0°C – 50°C (32°F - 50°F)
	Transport Temperature:	-20 – 50 °C (-4°F - 122°F)
	Rel. Humidity:	10 – 95% (non condensing)
Warm up time:		10 minutes at room temperature (20 °C) (68°F).
General		
PC control:	USB:	USB 1.1 or 2.0 for input/output for computer communication. Eclipse if fully operated from a PC
Construction:		Metal cabinet
Dimensions:		(L x W x H) 28 x 32 x 5.5 cm (11 x 12.6 x 2.2 Inches)
Weight:		2.5kg / 5.5 lbs excluding accessories

1.4 Technical Specifications EP15/EP25/VEMP

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	Safety:	IEC 60601-1, Class I, Type BF and IEC 60601-1-1, Class I, Type BF
	EMC:	IEC60601-1-2
	Test Signal:	IEC 60645-1/ANSI S3.6 IEC 60645-3 IEC 60645-7, Type 1
EPA Preamplifier:	Two channels standard	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional)	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB/60 dB
	Frequency response:	0,5 - 5000 Hz
	CMR Ratio:	Minimum >118 dB. Typical 130 dB < 100 Hz
	Radio frequency immunity:	Typically 25 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	10 MΩ/ 170 pF
Power from main unit:	Insulated power supply with 1500 V isolation. The signal is digitally/capacitive insulated.	
Specifications as EPA4	Impedance measurement:	Selectable for each electrode
	Measurement frequency:	33 Hz
	Waveform:	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
	Stimulus:	Stimulus rate:
	Envelopes/Windows :	Bartlett, Blackman, Gaussian, Hamming, Hanning, Rectangle and Manual (Rise/Fall and Plateau)
	Masking:	White noise. Calibrated and presented in peSPL.
	Transducer:	Ear Tone ABR insert phone, calibrated on an IEC 711 coupler. Headphone with independent calibration (optional) Bone conductor (optional)
	Level:	20 – 135.5 dB peSPL, (-10 – 100 dB nHL) in 1 dB steps.
	Polarity:	Condensation, Rarefaction, Alternating.
	Click:	100 µs (200Hz -11kHz)
	Tone Burst Frequency:	250, 500, 750, 1000, 1500, 2000, 3000, and 4000 Hz.
	Tone Burst Stimulation Time:	Stimulation up to 780 ms
	NB CE-Chirp® LS Freq.:	500, 1000, 2000 and 4000 Hz
	Broadband CE-Chirp®: LS	200Hz -11kHz
	Masking Level:	+30dB to -40 dB relative to stimulus presented in peSPL.
Recording:	Analysis Time:	-150 ms prior to stimuli and up to 1050 ms (license dependant).

	A/D Resolution:	16 bit.
	Sampling frequency	30 kHz
	Artifact Reject System:	Standard voltage based system
	Rejection levels:	Manual 0.2 - 640 μ V input wuth 0.1uV steps.
	Anti aliasing filter:	Analog 5kHz, 24 dB / octave
	Dots per Trace:	450 displayed.
	Low Pass Filter:	None or 17 – 12000 Hz, depending on the measurement type. 33 taps FIR Filter without wave peak latency displacement.
	High Pass Filter:	0.83 Hz to 500 Hz depending on the measurement type.
	DSP Low Pass Filter:	100, 300, 750, 1k, 1,5k, 2k, 3k, 4k, 5k, 7,5k Hz
	DSP High Pass Filter:	0.5, 1.0, 3.3, 10, 33, 100 Hz
Display Gain:		General Display Gain. Applicable during testing. Single Curve Display Gain. Applicable during testing.
Controlled parameters:		Stimuli Rate, Number of stimuli, Polarity, Click, Tone Burst (Frequency, no. of sine waves, window), Stimulus intensity, Number of curves per intensity, Intensity (Ascending, Descending), Soft attenuator, Stimulus ear, Transducer, Masking level, Preliminary filter setting, Recording onset, Automatic next intensity (Wave repro level on screen), General Display Gain, Single Curve Display Gain, Baseline, Latency norm, Report templates, Print out, Manual stimulus to familiarization, Talk Forward,
Data collection:		Impedance test, Waveform buffer (A/B, Contra, Ipsi-Contra, A-B = Noise), Curve (Hide, Fixate, Merge, Delete), Online EEG, Waveforms storage in unlimited storage database.
Data Recovery:		Lost data due to crash of Windows® will in almost all cases be available upon re-establishing Windows® operation.

1.4.1 peSPL to nHL Correction Values

Toneburst ECochG/ABR15/ABR30/AMLR/Neuro/VEMP 0 dB 2-2-2 cycle linear envelope				Toneburst ALR/MMN dB 25-50-25 ms			
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone
250	28	32	74.5	250	17.5	27	67
500	23.5	23	69.5	500	9.5	13.5	58
750	21	19	61	750	6	9	48.5
1000	21.5	18.5	56	1000	5.5	7.5	42.5
1500	26	21	51.5	1500	9.5	7.5	36.5
2000	28.5	25	47.5	2000	11.5	9	31
3000	30	25.5	46	3000	13	11.5	30
4000	32.5	27.5	52	4000	15	12	35.5
ISO 389-6:2007				ISO 389-1:2000, ISO 389-2:1994, ISO 389-3:1994			
Click ECochG/ABR15/ABR30/AMLR/Neuro/VEMP 0 dB				Click ALR/MMN 0 dB			
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone
Click	35.5	31	51.5	Click	35.5	31	51.5
NB CE-Chirp® LS ECochG/ABR15/ABR30/AMLR/Neuro/VEMP 0 dB				NB CE-Chirp® LS ALR/MMN 0 dB			
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone
500	25.5	25	74	500	25.5	25	74
1000	24.0	21.0	61.0	1000	24.0	21.0	61.0
2000	30.5	27	50	2000	30.5	27	50
4000	34.5	29.5	55.0	4000	34.5	29.5	55.0
CE-Chirp® LS ECochG/ABR15/ABR30/AMLR/Neuro/VEMP 0 dB				CE-Chirp® LS ALR/MMN 0 dB			
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone
	31.5	27.0	51.0		31.5	27.0	51.0

Only toneburst correction values change for ALR & MMN testing.
For Click and CE-Chirps® LS, the same correction is applied.

1.5 Technical Specifications TEOAE25

Medical CE-mark:	The Medical CE mark indicates that Interacoustics AS meets the requirements of Annex II of the Medical Device Directive 93/42EEC. Approval of the quality system is made by TÜV – identification no 0123.	
Standards:	Safety:	IEC 60601-1 (General safety) Class I, Type BF IEC 60601-1-2 (EMC)
		IEC 60645-6 Type 2 Otoacoustic emissions IEC 60645-3 (Auditory Test Signals) IEC 60645-6, Type 1 & Type 2
Stimulus:	Type:	Click (Linear or Non-linear)
	Bandwidth:	500 – 5500 Hz
	Level:	50-90 dB SPL
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE/TEOAE25 probe (Accuracy 0.5 dB)
Recording:	Analysis time:	25 to 32000 samples
	Sampling frequency	30 kHz
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Artifact Reject System:	25 – 55 dB SPL or off. Applicable during testing
	SNR Criteria:	5 individual frequency bands can be set 1-30 dB SPL
Display gain:	General Display gain:	Applicable during testing

OAE Probe Specifications:		
Probe:	Application:	TEOAE measurements
	Dimensions:	(W x D x H) 12 x 26 x 11 mm (exc. Eclipse)
Weight:		3 g (exc. Cable, exc. Eclipse)
		39 g (incl. cable, exc. Eclipse)
Cable:	Length:	2980 mm cable

TEOAE Calibration:

Probe stimuli are calibrated in peSPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.

1.6 Technical Specifications DPOAE20

Medical CE-mark:	The Medical CE mark indicates that Interacoustics AS meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no 0123.	
Standards	Safety:	IEC 60601-1 (General safety) Class I, Type BF IEC 60601-1-2 (EMC)
		IEC60645-6 Type 2 Otoacoustic emissions IEC 60645-3 (Auditory Test Signals) IEC 60645-6, Type 2
Stimulus:	Frequency Range:	500-8000 Hz
	Frequency Step:	50 Hz
	Level:	30-75 dB SPL (70 dB above 6kHz)
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE20/TEOAE25 probe
Recording:	Analysis time:	minimum 2 sec to unlimited test time
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Sampling frequency	30 kHz
	Artifact Reject System:	-30 – 30 dB SPL or off. Applicable during testing
	Stimulus Tolerance:	Adjustable
	SNR Criteria:	Adjustable
	Probe check window	256 points frequency response of the ear canal due to a click stimulus presented with a rate of 100 Hz at 80 dB SPL
	DP-Response window	4096 points frequency response
Display gain:	General Display gain:	Applicable during testing

OAE Probe Specifications:		
Probe:	Application:	DPOAE measurements
	Dimensions:	(W x D x H) 12 x 26 x 11 mm (exc. Eclipse)
	Weight:	3 g (exc. Cable, exc. Eclipse) 39 g (incl. cable, exc. Eclipse)
Cable:	Length:	2980 mm cable

DPOAE Calibration:

Probe stimuli L1 and L2 are calibrated individually in SPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.

1.7 Technical Specifications ABRIS

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	Safety:	IEC 60601-1, Class I, Type BF and IEC 60601-1-1, Class I, Type BF
	EMC:	IEC 60601-1-2
	Test signal	IEC 60645-1/ANSI S3.6 IEC 60645-3 IEC 60645-7, Type 2
EPA Preamplifier:	Two channels standard:	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional):	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB/60 dB
	Frequency response:	0,5 - 5000 Hz
	CMR Ratio:	Minimum >118 dB. Typical 130 dB < 100 Hz
	Radio frequency immunity:	Typically 25 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	10 MΩ/ 170 pF
	Power from main unit:	Insulated power supply with 1500 V isolation. The signal is digitally/capacitive insulated.
Specifications as EPA4 Impedance measurement:		Selectable for each electrode
	Measurement frequency:	33 Hz
	Waveform:	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:	Stimulus rate:	93 Hz
	Level:	30, 35, 40 dBnHL
	Click:	100 µs
Recording:	Analysis time:	120 seconds
	A/D resolution:	16 bit
	Sampling frequency	30 kHz
	Artifact rejection system:	Standard voltage based system
Display:	Stimulus level and type, Graph view	
Security:	Password protection of test parameters possible.	
Algorithmic Sensitivity:	Click:	99.99%
Specificity:	Click:	≥ 97%

1.8 Technical Specifications ASSR

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	Test signal:	IEC 60645-1/ANSI S3.6 (Audiometers) IEC 60645-3 (Auditory test signals)
EPA Preamplifier:	Two channels standard:	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional):	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB/60 dB
	Frequency response:	0,5 - 5000 Hz
	CMR Ratio:	Minimum >118 dB. Typical 130 dB < 100 Hz
	Radio frequency immunity:	Typically 25 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	10 MΩ/ 170 pF
Impedance measurement:	Waveform:	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:	Stimulus rate:	40 or 90 Hz
	Transducer:	Ear Tone ABR insert phone, calibrated on an IEC 711 coupler. HEADPHONE with independent calibration (optional) Bone conductor (optional)
	Level:	0 – 100 dB nHL in 5 dB steps.
	NB CE-Chirp® Freq.:	500, 1000, 2000, and 4000 Hz, both ears same time.
	Bandwidth:	1 octave ± ½ octave – 3 dB
	Masking:	White noise 0 – 100 dB SPL
	Analysis Time:	6 minutes to detect a ASSR signal – can be extended up to 15 minutes
Recording:	Sampling frequency:	30 kHz
	Artifact Reject System:	Standard voltage based system
	Gain:	74 – 110 dB. Auto or Manual selection.
	Channels:	2, with separate detection algorithm
	Algorithmic Sensitivity:	99% or 95% , false pass probability
	Rejection levels:	Manual 5, 10, 20, 40, 80, 160, 320, 640 µV input
	Anti- aliasing filter:	Analog 5kHz, 24 dB / octave
Display:	Independent control of up to 8 simultaneous stimuli (max 4 per ear)	
Display Gain:	Independent start, stop control for each of the 8 stimuli	
Controlled parameters:	Stimulus level control for each of the 8 stimuli	
	False pass probability 1 or 5%	
	Test protocols included for children and adult	
NOAH:	NOAH compatible (NOAH 3.6 or higher) tested compability for NOAH 4.4, 4.3, 4.2, 4.1, 4.0 and 3.6 (Estimated Audiogram available for other NOAH modules)	

1.9 Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the Eclipse Install and operate the Eclipse according to the EMC information presented in this chapter.

The Eclipse has been tested for EMC emissions and immunity as a standalone instrument. Do not use the Eclipse adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Eclipse is intended for use in the electromagnetic environment specified below. The customer or the user of the Eclipse should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Eclipse uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Eclipse is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	


Recommended separation distances between portable and mobile RF communications equipment and the Eclipse			
The Eclipse is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Eclipse can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Eclipse as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Eclipse is intended for use in the electromagnetic environment specified below. The customer or the user of the Eclipse should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the Eclipse requires continued operation during power mains interruptions, it is recommended that the Eclipse be powered from an uninterruptable power supply or its battery.

	<5% <i>UT</i> (>95% dip in <i>UT</i>) for 5 sec		
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: <i>UT</i> is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The Eclipse is intended for use in the electromagnetic environment specified below. The customer or the user of the Eclipse should assure that it is used in such an environment,

Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the Eclipse, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where <i>P</i> is the maximum output power rating of the transmitter in watts (<i>W</i>) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,5 MHz	3 V/m	

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Eclipse is used exceeds the applicable RF compliance level above, the Eclipse should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Eclipse
^(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

ITEM	MANUFACTURER	MODEL
EPA Preamplifier	Interacoustics	-
EPA3 Cable Collector	Interacoustics	-
EPA4 Cable Collector	Interacoustics	-
LBK 15 Loop Back Box	Interacoustics	LBK15
Insert Phones	Etymotic research	EarTone ABR
Headphone	Interacoustics	DD45s
Bone	Radio Ear	B71
OAE Probe	Interacoustics	Opt25
Cochlear Nucleus Trigger Cable	Interacoustics	Cochlear Nucleus
Optical USB 1.1 MED	Mailhaus	1.1 MED

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened
Mains Cable	2.0m	Unscreened
USB Cable	2.0m	Screened
EPA Preamplifier	2.5m	Screened
EPA3 Cable Collector	0.5m	Screened
EPA4 Cable Collector	50mm/0.5m/2.9m	Screened
LBK 15 Loop Back Box	2.0m	Screened
Insert phone	2.9m	Screened
Headphone	2.9m	Screened
Bone	2.0m	Screened
OAE Probe	2.9m	Screened
Cochlear Nucleus Trigger Cable	1.5m/5m	Screened

Essential performance

For this product the following is considered essential performance:

- To generate and present stimulus signals in the audio range as specified in the applicable IEC 60645 series in normal condition
- Record and store patient response